Section 5: 510(k) Summary

K080238

MAY 12 2008

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Contact for this Submission:	Marguerite Thomlinson, Manager, Regulatory Affairs
Date Summary Prepared:	January 28, 2008
Trade Name	Masimo Rainbow SET® Radical 7 CO-Oximeter
Common Name	Pulse Oximeter and Sensor
Classification Name	Oximeter (74DQA) Transducer and Electrode Cable (including connector) (74DSA) Carbon monoxide test system (JKS)(862.3220)
Substantially Equivalent Devices	Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and Accessories 510(k) Number – K061204 Masimo Rainbow SET® Rad 57cm/m Pulse CO-Oximeters and Accessories 510(k) Number – K053477 Radiometer America, Inc. OSM3 Hemoximeter 510(k) Number – K853990

Description of the Device

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories (Radical 7), the Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories (Rad 87), and the Masimo Rainbow SET® Rad 57t Pulse CO-Oximeter and accessories (Rad 57t) have the noninvasive monitoring Masimo Rainbow SET technology.

The Radical 7 provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, carboxyhemoglobin saturation (%SpCO), methemoglobin saturation (%SpMet), and/or total hemoglobin concentration (g/dl SpHb). Other information displayed by the Radical 7 include: Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), Total Arterial Oxygen Content (CaO_2), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Radical 7 has output interfaces include: SatShare connection to multi-parameter monitors, Nurse Call analog output, and RS-232 serial output.

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The Rad 87 provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, carboxyhemoglobin saturation (%SpCO), methemoglobin saturation (%SpMet), and/or total hemoglobin concentration (g/dl SpHb). Other information displayed by the Rad 87 include: Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), Total Arterial Oxygen Content (CaO_2), alarm status, alarm silence, battery life, sensor status, and trends. The Rad 87 has output interfaces include: Nurse Call analog output, and RS-232 serial output.

The Rad 57t provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, cand/or total hemoglobin concentration (g/dl SpHb). Other information displayed by the Rad 87 include: Low Signal IQ (Low SIQ), Perfusion Index (PI), Total Arterial Oxygen Content (CaO_2), alarm status, alarm silence, battery life, sensor status, and trends.

The Radical 7, Rad 87, and Rad 57t are intended to be used with Masimo LNOP series of oximetry sensors and patient cables, Masimo LNCS series of oximetry sensors and patient cables, Masimo Rainbow (SpCO/SpMet) sensors and patient cables, and Masimo Rainbow (SpCO/SpMet/SpHb) sensors and patient cables.

Intended Use/Indications for Use

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) to multi-parameter devices for the display of those devices.

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Masimo Rainbow SET® Rad-57 t Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo SET® Rad-57 t Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Principles of Operation

SpO_2 General Description

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects directly to the pulse oximetry instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two

ways: 1) as a percent value for arterial oxygen saturation (SpO_2), and 2) as a pulse rate (PR). Figure 1 shows the general monitoring setup..

SpCO, SpMet, and SpHb General Description
Instruments containing Masimo Rainbow SET technology also offer a continuous and non-invasive method of measuring the levels of carboxyhemoglobin concentration (SpCO), methemoglobin concentration (SpMet) and total hemoglobin in blood (SpHb). It relies on the same principles of pulse oximetry to make SpCO, SpMet and SpHb measurements. The measurements are taken by placing a sensor on a patient, usually on the fingertip for adults. The sensor connects directly to the instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage values for the SpCO and the SpMet and as grams/deciliter (g/dL) for SpHb. Instruments containing Masimo Rainbow SET technology are a combined SpO_2, SpCO, SpMet and SpHb monitor with the same setup as that of a pulse oximeter, shown above, and can display percentage or concentration values for SpCO, SpMet and SpHb as well as SpO_2 and pulse rate.

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light.
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Instruments containing Masimo Rainbow SET technology use a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, blood with oxidized hemoglobin and blood plasma. Signal data is obtained by passing various visible and infrared lights (LED's, 620 to 1270 nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle (see Figure 3). The photodetector receives the light, converts it into an electronic signal and sends it to the Radical 7/ Rad 87/ Rad-57t for calculation.

Once the instrument containing Masimo Rainbow SET technology receives the signal from the sensor, it utilizes Masimo Signal Extraction Technology (SET) to calculate the patient's functional oxygen saturation (SpO2), fractional concentration of carboxyhemoglobin (SpCO), fractional concentration of methemoglobin (SpMet), total hemoglobin concentration (SpHb) and pulse rate (PR). In instruments containing Masimo Rainbow SET technology, multi-wavelength calibration equations are used to estimate the saturation and concentration values.

Method of Operation

The Radical 7, Rad 87, and the Rad 57t have the same method of operation. The instrument is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the instrument.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. Depending on the type and/or configuration of the instrument, monitoring information would also include SpCO, SpMet, SpHb, PVI, and/or CaO_2. The practitioner can then use the information to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the CO-oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

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Specifications

The specifications for the Radical 7, Rad 87, and Rad 57t are:

FEATURES	SPECIFICATIONS	TYPE OF PULSE CO-OXIMETER
Display Ranges		
	Saturation (SpO_2): 0% - 100% Pulse Rate (bpm): 25 – 240 bpm Total Hemoglobin (SpHb): 0-25 g/dl Total Oxygen Concentration (CaO_2): 1-100 ml/dl Perfusion Index: 0.02% - 20%	Radical 7 Rad 87 Rad 57t
	Carboxyhemoglobin Saturation (SpCO): 0-99% Methemoglobin Saturation (SpMet): 0-99.9% Pleth Variability Index: 0% - 100%	Radical 7 Rad 87
Accuracy: SpO_2 and Pulse Rate	See Footnotes 1, 2, 3, 4, and 5	
Accuracy – SpO_2 During No Motion Conditions	Adults, Pediatrics, Infants: 60% - 80% ± 3% Adults, Pediatrics, Infants, Neonates: 70% - 100% ±2% Adults, Pediatrics, Infants, Neonates: 0% - 69% unspecified	Radical 7 Rad 87 Rad 57t
Accuracy – SpO_2 During Motion Conditions	Adults, Pediatrics, Infants, Neonates: 70% - 100% ± 3% Adults, Pediatrics, Infants, Neonates: 0% - 69% unspecified	Radical 7 Rad 87 Rad 57t
Accuracy – SpO_2 Low Perfusion	Adults, Pediatrics, Infants, Neonates: 70% - 100% ± 2% Adults, Pediatrics, Infants, Neonates: 0% - 69% unspecified	Radical 7 Rad 87 Rad 57t
Accuracy – Pulse Rate During No Motion Conditions	Adults, Pediatrics, Infants, Neonates: 25 - 240 ± 3 bpm	Radical 7 Rad 87 Rad 57t
Accuracy – Pulse Rate During Motion Conditions	Adults, Pediatrics, Infants, Neonates: 25 - 240 ± 5 bpm	Radical 7 Rad 87 Rad 57t
Accuracy – Pulse Rate Low Perfusion	Adults, Pediatrics, Infants, Neonates: 25 - 240 ± 3 bpm	Radical 7 Rad 87 Rad 57t
Accuracy: SpCO	See Footnote 1	
Accuracy – SpCO During No Motion Conditions	Adults, Pediatrics, Infants: 1% - 40%±3%	Radical 7 Rad 87
Accuracy: SpMet	See Footnote 1	
Accuracy – SpMet During No Motion Conditions	Adults, Pediatrics, Infants, Neonates: 1% - 15%±1%	Radical 7 Rad 87

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FEATURES	SPECIFICATIONS	TYPE OF PULSE CO-OXIMETER
Accuracy: SpHb		
Accuracy – SpHb During No Motion Conditions	Adults, Pediatrics: 7 - 17 g/dl ±1 g/dl • SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 7 - 17 g/dl SpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.	Radical 7 Rad 87 Rad 57t
General		
Resolution	SpO_2: 1% Pulse Rate: 1 bpm SpHb: 0.1 g/dl	Radical 7 Rad 87 Rad 57t
Resolution	SpCO: 1% SpMet: 0.1%	Radical 7 Rad 87
Measurements	Low Signal IQ Perfusion Index (PI) Total Oxygen Concentration (CaO_2)	Radical 7 Rad 87 Rad 57t
Measurements	Pleth Variability Index (PVI)	Radical 7 Rad 87
Interfering Substances	• Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements • Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements. • Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements • Severe anemia may cause erroneous SpO_2 readings. • Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings. • Elevated levels of total bilirubin may lead to inaccurate SpO_2, SpMet, SpCO and SpHb readings	Radical 7 Rad 87 Rad 57t (Notes regarding SpCO and SpMet measurements are not applicable to Rad 57t)
Electrical	See Footnotes 6 and 7	
Power (AC)	Voltage Input Range: 100-230 Volt, 47-63 Hz	Radical 7 Rad 87
Batteries	Rechargeable	Radical 7 Rad 87
Batteries	Non-Rechargeable	Rad 57t
Circuitry	Microprocessor controlled	Radical 7

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FEATURES	SPECIFICATIONS	TYPE OF PULSE CO-OXIMETER
	Automatic self-test of oximeter when powered on Automatic setting of default parameters Automatic alarm messages Trend data output	Rad 87 Rad 57t
Firmware	Rainbow SET technology, MX-1 Board/Circuitry	Radical 7 Rad 87 Rad 57t
Mechanical		
Material	Polycarbonate/ABS Blend	Radical 7 Rad 87 Rad 57t
Environmental		
Operating Temperature	41°F to + 104°F (5°C to +40°C)	Radical 7 Rad 87 Rad 57t
Storage Temperature	-40°F to + 158°F (-40°C to +70°C)	Radical 7 Rad 87 Rad 57t
Relative Humidity	5% to 95% noncondensing	Radical 7 Rad 87 Rad 57t
Operating Altitude	Operating Altitude: 500 mbar to 1,060 mbar pressure; -1,000 ft to 18,000 ft (-304 m to 5,486m)	Radical 7 Rad 87 Rad 57t
Mode & Sensitivity		
Averaging Mode	General: 2, 4, 6, 8, 10, 12 and 16 seconds • With FastSat the averaging time is dependent on the input signal • For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds respectively • Maximum sensitivity mode fixes perfusion limit to 0.02%	Radical 7 Rad 87 Rad 57t
Sensitivity	APOD Normal Maximum	Radical 7 Rad 87 Rad 57t
Alarms		
Volume Level Adjustment: Pulse/Tone	OFF 25% to 100% in 4 increments	Radical 7 Rad 87
Volume Level Adjustment: Pulse/Tone	OFF 33% to 100% in 3 step	Rad 57t
Alarm Silence	120 seconds delay All mute: continuous silence	Radical 7 Rad 87 Rad 57t
Out of Limit Alarm: SpO_2, Pulse Rate, SpHb	High/low alarms	Radical 7 Rad 87 Rad 57t

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FEATURES	SPECIFICATIONS	TYPE OF PULSE CO-OXIMETER
Out of Limit Alarm: SpCO, SpMet	High/ low alarms	Radical 7 Rad 87
Sensor Condition Alarm	No Sensor Sensor Off Sensor Defect	Radical 7 Rad 87 Rad 57t
System	System failure	Radical 7 Rad 87 Rad 57t
Battery Alarm	Low battery	Radical 7 Rad 87 Rad 57t
Display and Indicators		
Data Display	SpO_2 (%) Pulse rate (bpm) SpHb (g/dl) Perfusion index (%) CaO_2 (ml/dl) Signal IQ Sensitivity indicator Sensor status Status messages Alarm status Battery status	Radical 7 Rad 87 Rad 57t
	SpCO (%) SpMet (%) Pleth variability index (%)	Radical 7 Rad 87
Output Interface		
SatShare Port	SatShare connection to Multiparameter monitors (SpO_2 only)	Radical 7
Analog output	Nurse Call	Radical 7 Rad 87
Serial Port (RS-232 connector)	PC/printer connetion Philips Vuelink RadNet Patient Safety Net Trends	Radical 7 Rad 87
Sensor connector	Trends	Rad 57t
Compliance		
EMC Compliance	EN 60601-1-2, Class B	Radical 7 Rad 87 Rad 57t
Electrical Safety	IEC 60601-1, UL 60601-1	Radical 7 Rad 87 Rad 57t
Type of Protection (AC Power)	Class 1	Radical 7 Rad 87
Type of Protection (battery power)	Internally Powered	Radical 7 Rad 87 Rad 57t
Degree of Protection-Patient Cable	Type BF-Applied Part	Radical 7 Rad 87

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FEATURES	SPECIFICATIONS	TYPE OF PULSE CO-OXIMETER
		Rad 57t
Degree of Protection – SatShare Cable	Type CF	Radical 7
Enclosed Degree of Ingress Protection from Solids/ Liquids	IPX1	Radical 7 Rad 87 Rad 57t
Mode of Operation	Continuous	Radical 7 Rad 87 Rad 57t

Footnotes

1 SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO_2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.

2 The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population weight.

3 The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

4 The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

5 The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

6 This represents approximate run time at the lowest indicator brightness and pulse tone turned off using fully charged battery.

7 If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20 to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

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Test Summary

The Radical 7, Rad 87, and Rad 57t complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the the Radical 7, Rad 87, and Rad 57t:

- Risk Analysis
- Design Reviews
- Biocompatibility Testing
- Performance Testing
- Safety Testing
- Environmental Testing
- Clinical Testing

Conclusions

The information in this 510(k) submission demonstrates that the Radical 7, Rad 87, and Rad 57t are substantially equivalent to the predicate device, with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2008

Ms. Marguerite Thomlinson
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K080238
Trade/Device Name: Masimo Rainbow SET Radical 7 Pulse CO-Oximeter and Accessories
Masimo Rainbow SET Radical 87 Pulse CO-Oximeter and Accessories
Masimo Rainbow SET Radical 57 t Pulse CO-Oximeter and Accessories
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, JKS, DPZ
Dated: May 6, 2008
Received: May 7, 2008

Dear Ms. Thomlinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known):

Device Name:

Masimo Rainbow SET Radical 7 Pulse CO-Oximeter and accessories
Masimo Rainbow SET Rad 87 Pulse CO-Oximeter and accessories
Masimo Rainbow SET Rad 57 t Pulse CO-Oximeter and accessories

Indications For Use:

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) to multi-parameter devices for the display of those devices.

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Masimo Rainbow SET® Rad-57 t Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rainbow SET® Rad-57 t Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use**

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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